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Learning path for patent examiners

Assessment of inventive step: chemical inventions: Advanced level

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Introduction

This publication, "Assessment of inventive step: chemical inventions, Advanced level", is part of the "Learning path for patent examiners" series edited and published by the European Patent Academy. The series is intended for patent examiners at national patent offices who are taking part in training organised by the European Patent Office (EPO). It is also freely available to the public for independent learning.

Topics covered include novelty, inventive step, clarity, unity of invention, sufficiency of disclosure, amendments and search. Also addressed are patenting issues specific to certain technical fields:

- patentability exceptions and exclusions in biotechnology
- assessment of novelty, inventive step, clarity, sufficiency of disclosure and unity of invention for chemical inventions
- the patentability of computer-implemented inventions, business methods, game rules, mathematics and its applications, presentations of information, graphical user interfaces and programs for computers
- claim formulation for computer-implemented inventions

Each publication focuses on one topic at entry, intermediate or advanced level. The explanations and examples are based on the European Patent Convention, the Guidelines for Examination in the EPO and selected decisions of the EPO's boards of appeal. References are made to the Patent Cooperation Treaty and its Regulations whenever appropriate.

The series will be revised annually to ensure it remains up to date.

Disclaimer

All references to natural persons are to be understood as applying to all genders.

Contents

Legal references

1. Learning objectives

Participants to this course will learn:

- The definition and jurisprudence concerning "expectation of success" and the "try and see" situation when assessing inventive step.
- The requirements of Article 56 EPC with regards to antibody related inventions based on technical facts.
- The special case of the kits of parts with instructions on a data carrier.

2. Inventive step in biotechnology: expectation of success

Obviousness occurs not only for the solution of a technical problem but also when there is a reasonable expectation of success (T 149/93).

A solution is obvious if the person skilled in the art would have followed the teaching of the prior art with a reasonable expectation of success.

Examples

A claim to anastrozole for use in treating early-stage breast cancer was supported by comparative data showing anastrozole to be better than tamoxifen even in early-stage breast cancer:

- Two drugs (anastrozole and tamoxifen) were known as cancer medications.
- Tamoxifen was particularly known for treating early-stage breast cancer.
- Anastrozole was known to be superior to tamoxifen in advanced-stage breast cancer.
- Early-stage and advanced-stage breast cancer have different requirements in treatment ("different clinical situation").
- The claim was considered not inventive. Finding anastrozole to be better than tamoxifen in early-stage breast cancer was not predictable but the skilled person had a "reasonable expectation of success" because anastrozole was also better in advanced-stage breast cancer.
- T 1577/11 concluded that, given the superior efficacy of anastrozole over tamoxifen in treating advanced breast cancer, there was a reasonable expectation it would also improve the treatment of early breast cancer compared with tamoxifen.

Legal references:

Art. 56 EPC, GL G-VII, 13, CL Book I.D.7.1

3. "Try and see" situation

When the prior art suggests testing an approach and neither the implementation nor the testing of the approach involves any difficulties, then the skilled person may be said to simply apply a "try and see" attitude, which can be a reason for denying inventive step.

A "try and see" situation is considered to have occurred if the skilled person, in view of the teaching in the prior art, has already clearly envisaged a compound or group of compounds and then carried

out routine tests to determine whether that compound/those compounds had the desired effect (T 889/02, T 542/03, T 1241/03, T 1599/06, T 1364/08).

In these situations, the concept of "reasonable expectation of success" does not apply.

Legal references:
Art. 56 EPC, CL Book I.D.7.2

4. Inventive-step assessment of antibodies

Antibody defined by **antigen specificity**:

"An antibody Y that binds to antigen X"

- In T 0582/95, the board ruled that if the antigen X was unknown and the antibodies against X were unknown, both novelty and inventive step could be acknowledged.

In T 0684/23, the board denied an inventive step for the first antibody to a known antigen. Such antibodies can nonetheless be considered inventive if the skilled person was not motivated or able to produce them.Antibody defined by **antigen specificity** and **structural features**:

- For example: "*Monoclonal antibody binding to X comprising a heavy-chain variable domain of SEQ ID NO:1* ***and*** *a light-chain variable domain of SEQ ID NO:2"*.
- The subject-matter of a claim defining a novel antibody to a known antigen can involve an inventive step if the application shows a surprising technical effect or there was no reasonable expectation of success in obtaining antibodies having the required properties. Examples of surprising technical effects include an unexpected improvement over prior-art antibodies in one or more properties, such as therapeutic activity, stability or immunogenicity, or an unexpected property not exhibited by prior-art antibodies.
- Inventive step cannot be established solely on the basis that an antibody is structurally different from the prior-artantibodies. Arriving at alternative antibodies by exclusively applying techniques known in the art is considered to be obvious to the skilled person. The fact that the antibody structure , i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody to be non-obvious.
- Nevertheless, antibodies can be inventive if the application overcomes technical difficulties in producing or manufacturing the claimed antibodies. A novel type of functional antibody format may also be considered inventive.

Antibody defined by **antigen specificity** and **functional features**:

Examples

When assessing inventive step for an antibody defined by functional features the following questions can be helpful:

- Was the function known/suggested as being desirable?
- Are there routine ways to generate or select antibodies having that function?
- Is the scale of improvement predictable?

If the answer to any of them is yes, inventive step cannot be acknowledged.

Legal references:
Art. 56 EPC, GL G-II, 6.2, T 0582/95, T 0684/23

5. Kits-of-parts with instructions on a data carrier

The boards of appeal describe a "kit-of-parts" as the juxtaposition of separate but functionally interacting individual components.

Kits-of-parts with instructions on a data carrier are mixed-type inventions in that they are characterised by features which as such are technical in combination with features which as such are non-technical. The instructions are merely a presentation of information and as such non-technical.

According to Guidelines G-VII, 5.4, when applying the problem-solution approach to "mixed-type" inventions, all of the features which contribute to the technical character of the invention must be taken into account. This includes features which, when taken in isolation, are non-technical, but do, in the context of the invention, contribute to producing a technical effect serving a technical purpose (see also G-II, 3.1 to 3.7). Features defining a presentation of information thus have to be assessed in accordance with G-II, 3.7 in the context of inventive step and cannot be disregarded altogether under Article 52(2)(d) EPC; see also T 2948/18.

However, in the current practice of the EPO, instructions forming part of a kit-of-parts are generally assessed as not contributing to the technical character of the invention, so that they cannot support the presence of a inventive step.

Examples

Claim 1: *A method for diagnosing disease X comprising measuring marker Y by adding reagent A and reagent B to a sample leading to a change in colour which indicates disease X.*

Claim 2: *A kit (for carrying out the method) comprising reagents A and B and instructions for carrying out the method of claim 1 on a data carrier*.

Claim 2 is distinguished from D1 on account of the instructions for carrying out the method of claim 1.

The instructions correspond to static or predetermined information about using the claimed reagents in the method as claimed, the effect of which is merely the non-technical effect of exempting the user from knowing or memorising how to carry out the method. The instructions therefore do not, in the context of the kit being a product, contribute to the technical character of the invention.

Claim 1 therefore lacks inventive step.

Legal references:
Art. 56 EPC, GL G-VII, 5.4, G-II, 3.7.1, T 2948/18

6. Beyond the course

You can deepen what you have learned during this course with the following further readings:

- Further reading 1: Sela-Culang I, Kunik V, Ofran Y. The structural basis of antibody-antigen recognition. Front Immunol. 2013 Oct 8;4:302. doi: 10.3389/fimmu.2013.00302. PMID: 24115948; PMCID: PMC3792396.

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